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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/708,964	11/08/2000	Philip A. Beachy	JHUC-P04-010	3944
28120	7590	02/03/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			BADIO, BARBARA P	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 02/03/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/708,964

Applicant(s)

BEACHY ET AL.

Examiner

Barbara P. Badio, Ph.D.

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1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,15-17,20,22,23,27,28,36-39 and 41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,15-17,20,22,23,27,28,36-39 and 41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>07/26/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

First Office Action on the Merits of a RCE

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 13, 2004 has been entered.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

3. **The rejection of the instant claims under the judicially created doctrine of obviousness-type double patenting over claims of US Patent No. 6,432,970 is made moot by the filing of a terminal disclaimer.**

Claim Rejections - 35 USC § 112

4. Claims 1, 15-17, 20, 22, 23, 27, 28, 36-39 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in

such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite the utilization of “a purified organic molecule having a molecular weight less than 750 amu, wherein the organic molecule interacts with smoothened and lessens the severity of a hedgehog gain-of-function function, patched loss-of-function, or smoothened gain-of-function phenotype”. In order to satisfy the written-description requirement, the present specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing (see MPEP § 2163). In other words, the specification should contain written description of the claimed invention in **full, clear, concise** and **exact** terms to enable the skilled artisan in the art to **make and use** the same. The presently claimed invention as a whole is not adequately described in the present specification because there is a lack of correlation between the recited functions/properties and the structure of compounds called for. At best, the present specification requires that the skilled artisan should run test(s) on a wide spectrum of compounds having molecular weight less than 750 amu in the hope of finding compound(s) that will work.

5. The rejection of claims 1, 15-17, 20, 22, 23, 27, 28, 36 and 37 under 35 USC 112, first paragraph, scope of enablement is maintained and claims 38, 39 and 41 are rejected under 35 USC 112, first paragraph, scope of enablement.

According to applicant, a considerable amount of experimentation is permissible, if it is merely routine. Applicant also argues (a) the claims are not single means claims as numerous alternative means are possible, (b) not everything necessary to practice the invention need to be disclosed and (c) the skilled artisan would readily have been able to identify additional compounds within the scope of those recited by the instant claims with the use of chemical libraries. Applicant's argument was considered but not persuasive for the following reasons.

According to 35 USC 112, the specification must teach those of skill in the art how to make and use the full scope of the claimed invention without "undue experimentation". As stated by applicant and noted in MPEP § 2164.08, not everything necessary to practice the invention need to be disclosed. However, MPEP § 2164.08 also stated that the scope of enablement must bear a "reasonable correlation" to the scope of the claims. The present specification lacks correlation between the structure of the claimed compounds necessary to practice the claimed invention and the properties recited by the instant claims. Therefore, in order to practice the full scope of the claimed invention, the skilled artisan would have to screen every compounds having molecular weight less than 750 amu that would fall within the scope of the claimed invention. Because of the lack of guidance as to the structural correlation between the claimed compound(s) and the claimed properties, the amount of experimentation necessary to practice the full scope of the instant claims would impose an undue burden on the ordinary artisan in the art.

Applicant also argues the claims are not single means claims as numerous alternative means are possible. However, according to MPEP § 2164.08(a), "means" would refer to the compounds covered by the instant claims whereas the recited properties/function would be the "result". In the present situation, the claimed invention covers every conceivable structure having a molecular weight less than 750 amu (means) for achieving the claimed purpose and, thus, would be "single means" claims.

For these reasons and those given in previous Office Actions, the rejection of claims 1, 15-17, 20, 22, 23, 27, 28, 36 and 37 under 35 USC 112, first paragraph, scope of enablement is maintained and claims 38, 39 and 41 are rejected under 35 USC 112, first paragraph, scope of enablement.

Claim Rejections - 35 USC § 102

6. The rejection of claims 1, 20, 36, 38 and 39 under 35 USC 102(b) over Gerashchenko et al. is withdrawn.

Claim Rejections - 35 USC § 103

7. The rejection of claims 15-17, 22, 23, 27, 28 and 37 under 35 USC 103(a) over Gerashchenko et al. is withdrawn.

8. The examiner requests an update of the specification by incorporating the status of the parent applications.

Allowable Subject Matter

8. The examiner notes that the claimed invention is allowable to the extent it read on the elected Group, i.e., the method as claimed by the instant claims utilizing compounds having the chemical skeleton as cyclopamine or jervine.

Note: Seco-, nor- or homo-derivatives of said compounds are not included in said Group because they would have the basic chemical skeleton of the elected group.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary L. Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1616

BB

January 27, 2005